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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,114	08/25/1999	JOHN A. ARCADI	35687/RW/H29	6120
23363	7590	08/31/2004	EXAMINER	
CHRISTIE, PARKER & HALE, LLP			COOK, REBECCA	
PO BOX 7068				
PASADENA, CA 91109-7068			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/383,114	Applicant(s) ARCADI, JOHN A.	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 are is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1, 20-24, 28 and 29 are again rejected under 35 U.S.C. 112, first paragraph for the reasons given in the Paper of March 5, 2004, because the specification, while being enabling for using Rhodamine-123 to treat prostate cancer, does not reasonably provide enablement for treating any and all carcinomas. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that undue experimentation is not required to practice the invention. They further argue that the clinical tests required to demonstrate effective treatment are similar to the monoclonal antibody technology involved in *In re Wands*. This is not persuasive. Monoclonal antibodies involve in vitro testing and are more predictable than treating cancer. It is well established that there is no known anticancer agent which is effective against all cancers. Furthermore, applicants have not presented an assay which can be used as a model to demonstrate the effectiveness of Rhodamine-123 to treat all cancers.

Claims 9-12, 14 and 16 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amounts of ethyl alcohol recited in claims 13 and 15, does not reasonably provide enablement for any and all amounts of ethyl alcohol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate

in scope with these claims. Applicant argues that the claims should be read in light of the specification. This is not persuasive. In the absence of an explicit definition in the specification, claims are to be given their broadest reasonable interpretation.

In view of applicant's arguments and amendments to the claims the earlier rejections under 35 USC 112, paragraph two are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Arcadi in view of 5,880,141 (Tang et al) or EMBASE 94148842 and further in view of MEDLINE AN 93172422 for the reasons given in the Paper of March 5, 2004.

Applicant argues that there is no teaching in the references for combining them to achieve the applicant's invention and the Office does not identify any reason for such combination. This is not persuasive.

Arcadi discloses that Rhodamine-123 in saline solution (Rh-123) is effective against prostate cancer. Arcadi does not disclose a composition comprising Rh-123 and ethyl alcohol and sugar. However, Tang discloses that a cosolvent system comprising ethanol and dextrose (D5W) is known in the pharmaceutical art and that it produces low toxicity upon systemic administration. Furthermore, EMBASE 9414882

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discloses that ethanol enhances drug solubility. One of ordinary skill in the art would be motivated to use a composition comprising Rh-123 and ethanol because EMBASE 9414882 discloses that ethanol enhances drug solubility. One would further be motivated to use sugar because Tang discloses that ethanol and D5W produces low toxicity upon systemic administration.

Furthermore, one skilled in the art would be motivated to measure PSA levels before and after treatment because as disclosed by MEDLINE AN 93172422, it is well-known in the management of prostate cancer to measure PSA both pre and post treatment.

Bernal is considered cumulative and is no longer applied.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook

A handwritten signature in cursive script, appearing to read 'Rebecca Cook', written in black ink.

Primary Examiner
Art Unit 1614

August 26, 2004